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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,080	06/19/2003	John L. Magnani	400068.413	7045

500 7590 01/23/2007  
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 5400  
SEATTLE, WA 98104

EXAMINER
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EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/601,080	Applicant(s) MAGNANI ET AL.	
	Examiner Nabila G. Ebrahim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt of Applicant's remarks and amendments to the claims dated 10/31/06 is acknowledged.

#### ***Status of Claims***

Claim 17 is pending in the application.

Claims 1-16, 18-20 are cancelled.

***Status of Office Action:*** Final

#### ***Claim Rejections - 35 USC § 112***

In view of canceling claims 1-16, and 18-20, the rejection of claims 17-20 under 35 U.S.C. 112, first paragraph is herein withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "wherein the compound is" then recite a Markush group in an incorrect form (it lacks the phrase "selected from the group consisting of"). Applicant is required to recite the fifteen structures in a correct Markush group.
2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "a compound covalently attached to angiogenesis inhibiting agent"; the claim does not recite the other compound, which is

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conjugated to the 15 compounds recited in the claim. In addition, the claim does not recite the site of the covalent attachment of the angiogenesis-inhibiting agent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

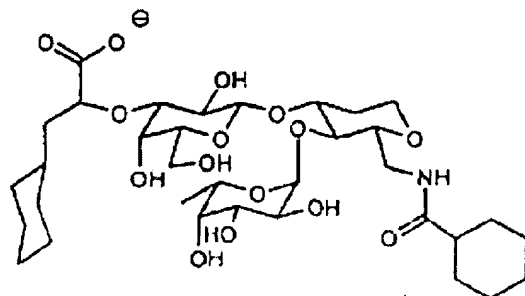
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Thoma et al. WO 9806730 "Thoma" in view of Liu et al. US 2002/0128225 for the reasons set forth in the office action dated 8/8/2006.

For facilitating the comparison made in the office action dated 8/8/2006 of compound 1 recited in instant claim 17, the figure is shown herein below which is compared to the structure of the compound in Thoma which is also shown with its written structure.

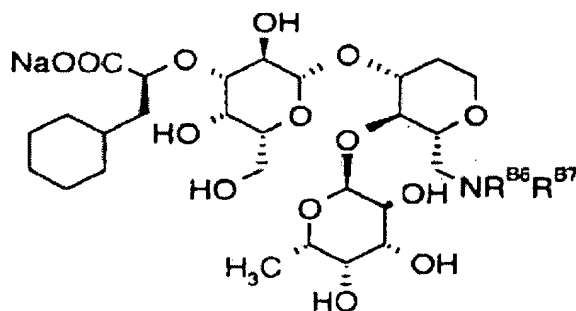
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**Compound 1 of instant claim 1**

$C_{34}H_{56}NO_{15}^-$   
Mol. Wt.: 718.81

1

Thoma

**Example B(b): Preparation of compounds of the formula I<sub>EX(b)</sub>**(I<sub>EX(b)</sub>)

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**(2) Preparation of compound No. B2b [R<sup>B6</sup>: H, R<sup>B7</sup>: C(O)C<sub>6</sub>H<sub>11</sub>]**

$C_{34}H_{56}NO_{15}Na$  (MW=741.80): MS (FAB positive mode, THG) 742 (M+H), 720 (M-Na+H), <sup>1</sup>H NMR (500 MHz, D<sub>2</sub>O) δ 4.86 (d, 1H, Fuc1), 4.67 (q, 1H, Fuc5), 4.48 (d, 1H, Gal1), 4.05-3.91 (m, 3H), 3.87 (d, 1H, Gal4), 3.83 (dd, 1H, Fuc3), 3.77 (d, 1H, Fuc4), 3.74 (dd, 1H, Fuc2), 3.72-3.68 (m, 2H), 3.63-3.55 (m, 3H), 3.53-3.40 (m, 4H), 3.36 (dd, 1H, Gal3), 2.27-2.16 (m, 2H), 1.79-1.68 (m, 5H), 1.68-1.47 (m, 9H), 1.37-1.08 (m, 11H, including at 1.17 (d, Fuc6)), 0.97-0.83 (m, 2H).

### ***Double Patenting***

1. In view of the abandonment of application 10/742,631 the rejection of claim 17 is herein withdrawn.
2. Claim 17 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/992,238 ('238). Although the conflicting claims are not identical, they are not patentably distinct from each other because: Instant claim 17 is drawn to a conjugate comprising a therapeutic agent linked to a compound according to Figure 1 and claim 10 of '238 recites the conjugation of similar compounds with a therapeutic or diagnostic agents.
3. Claim 17 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 10/992,480 ('480). Although the conflicting claims are not identical, they are not patentably distinct from each other because: Instant claim 17 is drawn to a conjugate comprising a therapeutic agent linked to a compound according to Figure 1 and claim 6 of '480 recite the same combination.

### ***Response to Arguments***

2. Applicant's arguments filed 10/31/06 have been fully considered but they are not persuasive. Applicant argues that:

Thoma et al. does not teach or suggest the use of the compounds disclosed therein to inhibit or promote angiogenesis. Thoma et al. also does not teach or suggest

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the conjugation of any of the compounds disclosed therein, and in particular does not teach or suggest conjugation to an angiogenesis-inhibiting agent.

**To respond:** the intent of use is not of weight in examining composition because the prior art composition could be able to achieve the same effect. In addition, in spite of the fact that Thoma did not disclose conjugates, Thoma disclosed that the compounds SLeX mimetics are having interesting binding affinity properties.

Applicant argues that:

The Office Action cites to Liu et al. for the conjugation of a glycomimetic to an antineoplastic drug. Applicants respectfully disagree. For example, Liu et al. nowhere teaches or suggests conjugates. In paragraph [0127] of Liu et al., there is mention of co-administration of anti-cancer drugs. However, co-administration is not conjugation, and covalent attachment (conjugation) is expressly required by the language of claim 17 as originally filed and as presently pending after amendment. Co-administration is described in Liu et al. at paragraph [0126] as the administration in cocktails. The components of the cocktails were not covalently attached to one another. A cocktail is simply one or more components in solution together. In paragraph [0126] of Liu et al., the cocktail is disclosed as containing a polysaccharide and an anti-cancer agent. Because the polysaccharide and the anti-cancer agent in a cocktail of Liu et al. are not conjugated (i.e., not covalently attached to one another), upon administration of the cocktail to a patient, the polysaccharide and the anti-cancer agent distribute themselves (in the patient's body) independent of one another.

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**To respond:** Lieu et al. suggests different chemical complexes and conjugates of different kinds of polysaccharide with other compounds including anticancerous drugs (such as cisplatin), see paragraph [0109]. Note that Thoma had already established the idea that SLeX mimetics are having interesting binding affinity properties while Lieu suggest different complexes and conjugates of anticancer drugs with polysaccharide.

### ***Double Patenting***

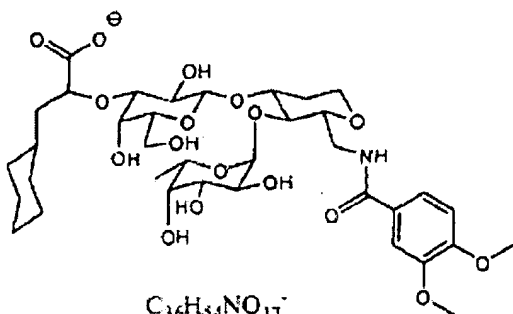
Applicant argues that: the compounds of the '238 Application are not "similar" to the compounds according to Figure 1 of the subject application. For example, the compounds according to Figure 1 of the subject application do not possess a BASA (Benzyl Amino Sulfonic Acid), whereas the compounds of the '238 Application do possess a BASA. Furthermore, since the '238 Application has yet to receive a first substantive Office Action, Applicants believe that it would be more appropriate to apply this rejection (if at all, given the structural differences between the compounds) in the '238 Application and not in the subject application.

**To respond:** Please review the compounds recited in instant claim 1, from structure 4.

Structure 4 in instant claim 17.



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$C_{36}H_{54}NO_{17}^-$   
Mol. Wt.: 772.81

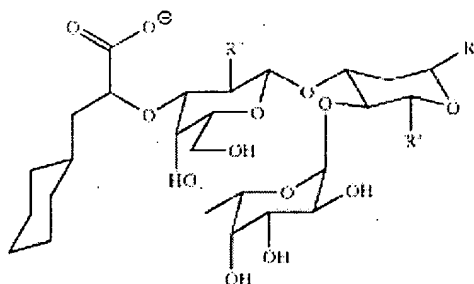
4

A part of claim 1 of application 10/992238

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What is claimed is:

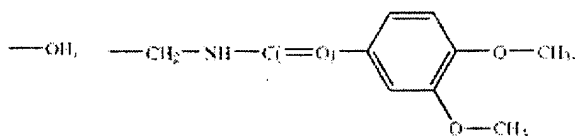
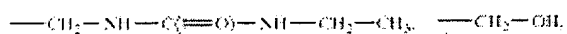
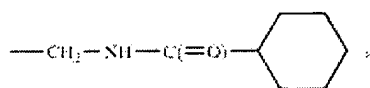
1. A compound or physiologically acceptable salt thereof, having the formula:



wherein:

R=H or a benzyl amino sulfonic acid;

R'=a benzyl amino sulfonic acid,



Applicant argues that: The compounds of the '480 Application are not similar to the compounds according to Figure 1 of the subject application. For example, the compounds according to Figure 1 of the subject application do not possess a BASA (Benzyl Amino Sulfonic Acid), whereas the compounds of the '480 Application do possess a BASA. Furthermore, since the '480 Application has yet to receive a first substantive Office Action, Applicants believe that it would be more appropriate to apply this rejection (if at all, given the structural differences between the compounds) in the '480 Application and not in the subject application.

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**To respond:** Please review the compounds recited in instant claim 1 structure 4.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim

1/16/07

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER